

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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R. LEDESMA

**New Animal Drugs for Use in Animal Feeds; Chlortetracycline, Procaine Penicillin, and Sulfamethazine**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the approved status of a new animal drug application (NADA) held by Pennfield Oil Co. The NADA provides for the use of three-way, fixed combination Type A medicated articles containing chlortetracycline, procaine penicillin, and sulfamethazine to make three-way combination drug Type C medicated swine feeds used for growth promotion, increased feed efficiency, and the management of several bacterial diseases. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to remove certain obsolete or redundant sections of the new animal drug regulations. That proposed rule contains background information about those regulations and also for this action.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Andrew J. Beaulieu, Center for Veterinary Medicine (HFV-1), 7519 Standish Pl., Rockville, MD 20855, 301-827-2954, e-mail: [abeaulie@cvm.fda.gov](mailto:abeaulie@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, holds an approval for NADA 138-934 for use of PENNCHLOR SP

250 and PENNCHLOR SP 500 (chlortetracycline, procaine penicillin, and sulfamethazine) three-way, fixed combination Type A medicated articles to make three-way combination drug Type C medicated swine feeds for use for growth promotion, increased feed efficiency, and the management of several bacterial diseases. This product is subject to the transitional approval provision of section 108(b)(2) of the Animal Drug Amendments of 1968 and is currently subject to interim marketing under § 558.15(g)(1) (21 CFR 558.15(g)(1)). At this time, 21 CFR 558.145 is being amended to reflect this approved application.

We note the drug sponsors designated for this product in § 558.15(g)(1), American Cyanamid Co. and Pfizer, Inc., are incorrect. Likewise, the provision states that the use levels and indications for use for this medicated article are listed in § 558.15(g)(2), but this information was apparently never listed in § 558.15(g)(2).

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

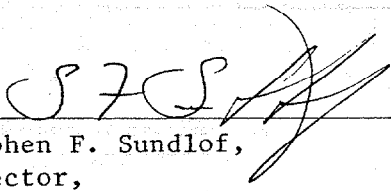
■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

**§ 558.145 [Amended]**

■ 2. Section 558.145 *Chlortetracycline, procaine penicillin, and sulfamethazine* is amended in paragraph (a)(2) by adding "and 053389" after "046573".

Dated: 8/1/03  
August 1, 2003.

  
Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

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